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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/762,079 | 01/21/2004 | Shubh D. Sharma | 70025-US04-497 | 4623 |

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EXAMINER

SACKY, EBENEZER O

ART UNIT

PAPER NUMBER

1624

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 02/05/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/762,079

Applicant(s)

SHARMA ET AL.

Examiner

EBENEZER SACKEY

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 59-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 16-29, 35-46, 48-55 and 58 is/are rejected.
- 7) ☒ Claim(s) 11-15, 30-34, 47, 56 and 57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/16/04; 09/26/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

This is in response to applicant's amendment filed on 11/02/06.

Status of the Claims

Claims 1-65 are pending.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on 09/16/04 and 09/26/05 respectively is acknowledged and has been entered into the file. Copies of the signed 1449 are attached herewith.

Response to Restriction

Applicant's election without traverse of Group I, claims 1-58 (in part), species of Example 47 in the reply filed on 11/02/06 is acknowledged. The said species is allowable, however, generic formula (I) is not deemed allowable.

Claim Objections

Claim 58 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative. See MPEP § 608.01(n). Accordingly, the claim 58 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1, 3, 6, 16-19, 22, 25, 35-38, 41, 44, 50, 53 and 56-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the term comprising in compound claims cited herein is inclusive and fails to exclude unrecited elements. The use of the term comprising to introduce claimed structure means that ingredients covered by these claims may involve more elements than those positively recited. *Ex Parte Davis et al.*, 80 U.S.P.Q. 448 (PTO Bd. App. 1948). Additionally, the metes and bounds of the terms "functionalized" and "cationic center" cannot be ascertained. Clarification is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

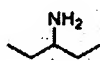
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).


Claims 1-9, 20-26, 28, 39-41, 44-45, 48-50, 52-54 and 58 are provisionally

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rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 12,13,14, 20-28, 30, 32, 34-40 of copending Application No. 11/099,814. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is considerable overlap between the current claims and claims from 11/099,814. The instant application discloses for the same purpose compounds and compositions, which are similar to the compounds and compositions of '814' for treating various ailments such as treating sexual dysfunction.

Substituents R^2 , R^3 , W, L_2Q , correspond similarly to y, R^6 , R^7 , W, of '814' with an overlap where R^2 is for example $(CH_2)_yW$, where W is as defined and R_3 is L_2-Q , where

L_2 is the linker  etc., and L_1-J etc are as defined. These correspond to '814'

where W is as defined, y is 0, Z is 1, R^6 is H, R^7 is NH_2 or  and L and J all have similar overlap.

Thus, the difference between the instant invention and '814' is that of generic description. The selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. inhibiting melanocortin receptor activity).

The claimed compounds would be obvious from the use of similar compounds and composition containing the compounds, which are inhibitors of melanocortin activity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

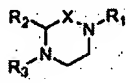
2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. Claims 1-10, 20-29, 39-46, 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bauman et al., (U.S. Patent number 6,207,665).

Applicants claim compounds and composition of structural formula (I), where the

substituents are as defined in the claims.  , where substituents are

R_1 is $-L_1-J$ or, if X is CH_2 , is H or $-L_1-J$;

R_2 is $(CH_2)_7-W$ or, if X is CH_2 , is H or $-L_1-J$, on the proviso that not R_1 and

R_3 are not both H ;

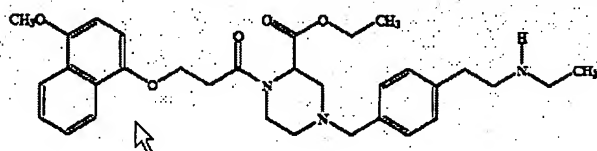
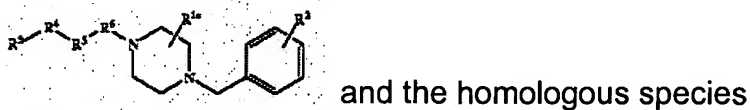
R_3 is $-L_2-Q$;

L_1 is a linker selected from the group consisting of $-(CH_2)_7-$, $-O-(CH_2)_7-$,

$-O-$, $-NH-(CH_2)_7-$, $-(C=O)(CH_2)_7-$, $-(C=O)-O-(CH_2)_7-$, and $-CH_2(C=O)NH-$; etc.

Determination of the scope and content of the prior art (MPEP §2141.01)

Bauman et al., teach acyl piperazine derivatives of structural formula (Ia) which are similar to the current compounds. See the entire reference especially column 3, lines 35 bridging columns 4-6. Bauman et al., read on the current claims when R^3 is a substituted carbocyclic system; R^4 is a bond; R^5 is a methylene chain substituted by $N(R^7)_2$ where R^7 is hydrogen; R^6 is $C(O)$ and R^{1a} is alkyl. See homologous species in column 25 and the various species cited in columns 31-41.



Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the current claims and Bauman et al., is in the generic description of the compounds. The indiscriminate selection of "some" among "many" is *prima facie* obvious. *In re Lemin*, 141 USPQ 814 (1964). The Bauman reference provides the necessary teaching and guidance to arrive at the instantly claimed

compounds. See *In re Baird*, 29 USPQ 2d. 1550 (1994) CAFC. Note '665' reference teaches a pharmaceutical use in the form of treating inflammatory disorders.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

The motivation to make the claimed compounds derives from the expectation that compounds structurally similar to the instant compounds would possess similar activity (i.e., altering disorders associated with melenocortin activity).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art to prepare instant compounds as disclosed by Bauman with a reasonable expectation of success absent a showing of unexpected results. Therefore, at the time of filing this application, one of ordinary skill in the art in possession of Bauman et al., would have been in possession of the instant compounds absent a showing of unexpected results and/or properties.

Allowable Subject Matter

Claims 11-15, 30-34, 47, 56-57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone

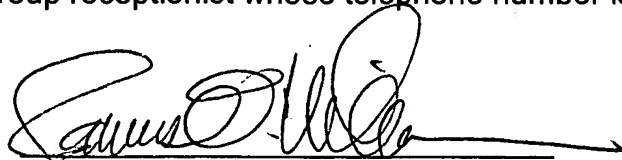
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number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS
January 26, 2007

A handwritten signature in black ink, appearing to read "James O. Wilson", with a long horizontal flourish extending to the right.

James O. Wilson
Supervisory Patent Examiner
Art Unit 1624, Group 1600
Technology Center 1